

PRELIMINARY AMENDMENT

Most ocular tumors metastasize from systemic origins in breast carcinoma in females, and bronchial carcinoma in males (Chen YR, et al., *Bilateral choroidal metastases as the initial presentation of a small breast carcinoma: a case report*, Chung Hua I Hsueh Tsa Chih (Taipei); 61(2):99-103, 1998). Antibody elicited to carcinoembryonic antigen (CEA), which is associated with the choroidal tumor, is conjugated to a benzoporphyrin derivative photosensitizing agent in a liposomal formulation. A drug dose of 10 mg/m² is administered via intravenous infusion over 10 min.

In the Claims:

Please replace claim 26 with the following claim.

26. The method of claim 25, wherein said first targeted tissue is abnormal endothelium that lines or composes neovasculature tissue; and said second targeted tissue is a tumor antigen.

REMARKS

Any fees that may be due in connection with this application throughout its pendency may be charged to Deposit Account No. 50-1213.

Claim 26 is amended to correct a minor typographical error.

The specification is amended to correct minor typographical and spelling errors and to produce grammatical clarity. The amendment to paragraph 005 on page 2, and paragraph 010 on page 4, of specification replaces the US Patent No. "5,6333,275" with the US Patent No. —5,633,275— to correct obvious typographical error. The amendment finds basis in the cited patent in which Mori *et al.* are the inventors of Patent No. 5,633,275, not 5,6333,275. The amendment to paragraph 007 on page 3, replaces the verb "are" with the verb —is— for grammatical clarity. The amendment to paragraph 063 on page 17, inserts the inadvertently omitted preposition "of" for grammatical clarity.

No new matter has been added.

U.S.S.N 09/760,362

Chen

PRELIMINARY AMENDMENT

Included as an attachment is a marked-up version of the specification paragraphs and claim 26, per 37 CFR §1.121.

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Entry of this amendment and examination of the application are respectfully requested.

Respectfully submitted,
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: JAMES CHEN

Serial No.: 09/760,362

Filed: January 12, 2001

For: *NOVEL TREATMENT FOR EYE
DISEASE*

Art Unit: 1614

Examiner: Unassigned

**ATTACHMENT TO THE PRELIMINARY AMENDMENT
MARKED UP PARAGRAPHS AND CLAIMS (37 CFR §1.121)**

IN THE SPECIFICATION:

Please amend the specification as follows:

Please amend paragraph 005 on page 2, as follows:

As an alternative to photocoagulation, photodynamic therapy has been proposed as a means of treating this form of AMD (see: Strong *et al.*, "Vision through photodynamic therapy of the eye," U.S. Patent Nos. 5,756,541 and 5,910,510; and Mori *et al.*, "Photochemotherapeutical obstruction of newly-formed blood vessels," U.S. Patent No. [5,633,275] 5,633,275).

Photodynamic therapy ("PDT"), as taught in this prior art, is a two-step treatment process. PDT is performed by first administering a photosensitive compound systemically or topically, followed by illumination of the treatment site at a wavelength or waveband of light from a laser which closely matches the absorption spectra of the photosensitizer. In doing so, singlet oxygen and other reactive species are generated leading to a number of biological effects resulting in damage to the endothelial membranes and ultimately to clotting of the neovasculature.

Please amend paragraph 007 on page 3, as follows:

retinopathy and age-related macular degeneration. The growth of new blood

PRELIMINARY AMENDMENT ATTACHMENT

vessels [are] is also associated with tumor formation in the eye, which results from two mechanisms: the stimulated growth of endothelial cells of existing blood vessels through angiogenesis; and a newly discovered vasculature resulting from highly malignant uveal melanomas, which develop in the eye, are full of networks of blood channels made by the melanoma cells themselves (Maniotis et al., *American Journal of Pathology* 155(3):739-52 (1999)). It may be that anti-angiogenic agents are ineffective in the treatment of such neovasculature arising not from endothelial cells, but from tumor cells such as those of malignant uveal melanomas.

Please amend paragraph 010 on page 4, as follows:

Regarding light sources for PDT, high powered lasers are usually employed in order to shorten the procedure time (see: Strong *et al.*, U.S. Patent Nos. 5,756,541 and 5,910,510; and Mori *et al.*, U.S. Patent No. [5,633,275] 5,633,275; see more generally, W.G. Fisher, *et al.*, *Photochemistry and Photobiology*, 66(2):141-155, 1997).

Please amend paragraph 037 on page 10, as follows:

"Illumination" as used herein includes all [wave length] wavelengths and wavebands. Preferably, the illumination [wave length] wavelength or waveband is selected to match the [wave length(s)] wavelength(s) or wavebands which excite the photosensitive compound. Even more preferably, the radiation [wave length] wavelength or waveband matches the excitation [wave length] wavelength or waveband of the photosensitive compound and has low absorption by the non-target tissues of the eye, and the rest of the subject, including blood proteins.

Please amend the paragraph 063 on page 17, as follows:

EXAMPLE 4 TREATMENT OF CHOROIDAL TUMOR OF THE EYE

Most ocular tumors metastasize from systemic origins in breast carcinoma in females, and bronchial carcinoma in males (Chen YR et al. *Bilateral choroidal*

U.S.S.N 09/760,362

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PRELIMINARY AMENDMENT ATTACHMENT

Antibody elicited to carcinoembryonic antigen (CEA), which is associated with the choroidal tumor, is conjugated to a benzoporphyrin derivative photosensitizing agent in a liposomal formulation. A drug dose of 10 mg/m² is administered via intravenous infusion over 10 min.

In the Claims:

Please amend claim 26, as follows.

26. The method of claim 25, wherein said first targeted [tissues] tissue is abnormal endothelium that lines or composes neovasculature tissue; and said second targeted tissue is a tumor antigen.